UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/761,150	01/20/2004	Jose Manuel Andreu Morales	1379-1-022	1559

7590 09/15/2006

KLAUBER & JACKSON
4th Fl
411 Hackensack Avenue
Hackensack, NJ 07601

EXAMINER	
FETTEROLF, BRANDON J	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 09/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/761,150	ANDREU MORALES ET AL.	
	Examiner	Art Unit	
	Brandon J. Fetterolf, PhD	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-18 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-18 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Application Status

Claims 1-18 are currently pending and under consideration.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 120 as to the PCT application, PCT/ES02/00262, filed on 05/31/2002 and priority under U.S.C. 119(a)-(d) as to Spanish Application Serial No. 200101710 is acknowledged. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. However, the Examiner has established a priority date of **1/20/2004** consistent with the instant application 10/761,150 because a certified copy of the international application and English translation of the international application have not been provided, see MPEP 1895.01. If applicant disagrees with any rejection of claims 1-18 set forth in this office action based on examiner's establishment of a priority date of **1/20/2004** for the instant claims in application serial number 10/761,150 applicant is invited to submit a certified copy of the international application (and an English translation) of the international application to perfect the claim for benefit under 35 U.S.C. 120 and U.S.C. 119 (a)-(d).

Information Disclosure Statement

The information disclosure statement filed on 05/12/2005 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered.

The Information Disclosure Statement filed on 2/06/2004 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner. A signed copy of the IDS is attached hereto.

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into

the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Objections

Claims 1, 3-6, 9, 12 and 15-16 are objected to because of the following informalities:

The format of claim 1 is unclear and confusing. The Examiner suggest amending claim 1 to recite a method of providing a homogenous test for the detection of any antitumor substance substitutive of paclitaxel in the paclitaxel binding site of microtubules, wherein said method is based on the combination of a target and a probe and comprises the following steps: adding a test substance or test substances to a solution of a target consisting of microtubules and a fluorescent probe bound to the target; determining the displacement of the probe by the test substance, wherein the displacement is determined by measuring the drop in anisotropy via the variation of the fluorescence intensity of the probe or the resonance energy transfer of the probe to a suitable acceptor; and identifying a biomimetic compound of paclitaxel, wherein the biomimetic compound is identified by a drop in anisotropy of the fluorescence of the probe or by means of the drop in resonance energy transfer to the probe bound to a ligand.

Claims 4-6 recite a series of fluorescent derivatives which appear to be misspelled. For example, claim 4 recites "7-O-[N-(2,7-dfluoro-4'-fluoresceincarbonyl)-L-alanyl]paclitaxel, 7-O-[N-(2,7-dfluoro-4'-fluoresceinsulphonyl)-- L-alanyl]paclitaxel, 7-O-[N-(4'-tetramethylrhodaminrecarbonyl)-L-alanyl]paclitaxel, and 7-O-[N-(2,7-dfluoro-4'-fluoresceincarbonyl)-L-beta-alanyl]paclitaxel". However, it appears that the claims should recite "7-O-[N-(2,7-difluoro-4'-fluoresceincarbonyl)-L-alanyl]paclitaxel, 7-O-[N-(2,7-difluoro-4'-fluoresceinsulphonyl)-- L-alanyl]paclitaxel, 7-O-[N-(4'-tetramethylrhodaminrecarbonyl)-L-alanyl]paclitaxel, and 7-O-[N-(2,7-difluoro-4'-fluoresceincarbonyl)-L-beta-alanyl]paclitaxel. Appropriate correction is required.

Claims 3, 6, 9, 12 and 15-16 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Diaz et al. (J. Biol. Chem. 2000; 275: 26265-26276, *IDS*).

Diaz et al. teach a method of providing a homogenous test for the detection of an antitumor substance in the paclitaxel binding site of microtubules, wherein said method is based on the combination of a target and a probe and comprises the following steps: adding a test substance or test substances to a solution of a target consisting of microtubules and a fluorescent probe bound to the target; determining the displacement of the probe by the test substance, wherein the displacement is determined by measuring the drop in anisotropy via the variation of the fluorescence intensity of the probe; and identifying a biomimetic compound of paclitaxel, wherein the biomimetic compound is identified by a drop in anisotropy of the fluorescence of the probe (page 26265, 2nd column, *Kinetics of Binding and Dissociation of Fluorescent Taxoids to Microtubules*, page 26267, 1st column and Figure 1). With regards to the microtubules, the reference teaches cross-linked microtubules assembled in vitro in GAB and preserved with glutaraldehyde, wherein the cross-linked microtubules were found to be stable against low temperatures and dilution (page 26266, 2nd column, Preparation of Cross-linked Microtubules). With regards to the probe, Diaz et al. teach two fluorescence taxoids, 7-*O*-[*N*-(4'-fluoresceincarbonyl)-L-alanyl]Taxol (Flutax-1) and 7-*O*-[*N*-(2,7-difluoro-4'-fluoresceincarbonyl)-L-alanyl]Taxol (Flutax-2) which bind to microtubules with high affinity (abstract). With regards to antitumor substance, e.g., a test substance, which binds to the paclitaxel binding site of microtubules, the reference teaches that docetaxel was used for displacing the fluorescent probes due to it ability to bind to the Taxol binding site and larger solubility (page 26267, 1st column, paragraph bridging page 26266). Moreover, the reference teaches that the fluorescence anisotropy of the samples was measured using a Spex spectroflurometer plate reader (page 26266, 2nd column, 4th full paragraph). Thus, while Diaz et al. do not explicitly teach the preambles recited in claims 13-18 which utilize the steps of the method of claim 1, a preamble is

generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. (emphasis added) See In re Hirao, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and Kropa v. Robie, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Claims 1-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Andreu et al. (Biochemistry 2001; 40: 11975-11984, *IDS*).

Andrue et al. teach a method of providing a homogenous test for the detection of an antitumor substance in the paclitaxel binding site of microtubules, wherein said method is based on the combination of a target and a probe and comprises the following steps: adding a test substance or test substances to a solution of a target consisting of microtubules and a fluorescent probe bound to the target; determining the displacement of the probe by the test substance, wherein the displacement is determined by measuring the drop in anisotropy via the variation of the fluorescence intensity of the probe and the resonance energy transfer to the probe bound to a suitable acceptor; and identifying a biomimetic compound of paclitaxel, wherein the biomimetic compound is identified by a drop in anisotropy of the fluorescence of the probe (entire document, specifically, page 11976, 2nd column, 1st full paragraph and page 11979, 2nd column, *Competitive Fluorescent Assay of Ligand Binding to Microtubules Measures the Binding of Taxol and Baccatin III*). With regards to the microtubules, the reference teaches cross-linked microtubules assembled in vitro and indefinitely conserved by means of dialysis against a conservation and cryopreservation buffer (page 11976, 1st Column, *Cross-Linked Microtubules*). With regards to the probe, Andrue et al. teach that the probe includes 7-*O*-[*N*-(2,7-difluoro-4'-fluoresceincarbonyl)-L-alanyl]Taxol (abstract). With regards to antitumor substance, e.g., a test substance, which binds to the paclitaxel binding site of microtubules, the reference teaches that docetaxel and baccatin III recognizes the Taxol binding site of microtubules (page 11979, 2nd column, *Competitive Fluorescent Assay of Ligand Binding to Microtubules Measures the Binding of Taxol and Baccatin III*). Moreover, the reference teaches that the fluorescence anisotropy of the samples was screened in 96-well plates using a microplate reader (page 11979, 2nd column, 1st full paragraph). Andrue et al. further teach that the method can be used to screen for Taxol mimetics such as evaluating the binding affinity of newly designed compounds of the Taxol,

epothilone, eleutherobin and discodermolide familes, as well as measuring the active Taxol-like contents of natural sources (page 11981, 2nd column, *Potential Uses of Fluorescence Anisotropy Multiwell Plate Assay in Comparison with Other Methods To Screen for Taxol Mimetics*). Thus, while Diaz et al. do not explicitly teach the preambles recited in claims 13-18 comprising the steps of the method of claim 1, a preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. (emphasis added) See In re Hirao, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and Kropa v. Robie, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Therefore, No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J. Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached on Monday through Friday from 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeff Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brandon J Fetterolf, PhD
Patent Examiner
Art Unit 1642

BF

JEFFREY SIEW
SUPERVISORY PATENT EXAMINER